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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,136	01/24/2002	Nobuyuki Tatsumi	NGB-12930	2328

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EXAMINER
GORDON, BRIAN R

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,136	TATSUMI, NOBUYUKI	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,13,14 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1, 5* is/are allowed.

6)☒ Claim(s) *3, 13-14, 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1-24-02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 31, 2005 has been entered.

Response to Arguments

Applicant's arguments filed May 31, 2005 have been fully considered but they are not persuasive. In anticipation of the following rejection applicant, has stated Sohrab clearly teaches away from the presently claimed invention. The examiner respectfully disagrees, for the absence of specific intended use within a disclosure does not necessarily constitute teaching away from that intended use. There is no specific mention within the disclosure of Sohrab that the micro-needle may not be employed to dispense/inject fluid into other target vessels such as an analyzer instrument. As such the claims have been rejected as follows.

As to claim 13 and 14, applicant merely asserts the references do not disclose the claimed combination, however, applicant does not disclose what specific elements are not disclosed.

The previous 102 rejections of claims 13 and 14 as based upon E-Hage et al. Li et al., and King et al. are hereby maintained.

In view of applicants, arguments/amendment the previous final rejections of the claims are hereby withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by El-Hage et al. US 5,843,378.

El-Hage et al. teaches aspirating and dispensing probes are often used to transfer liquids between various vessels (plurality of vessel) and compartments in a chemical analyzer. The liquids typically include samples to be tested and reagents for testing the samples.

The probe successively aspirates reagents from reagent vessels and transfers the reagents to the reaction cuvette. After the sample-reagent mixture incubates in the reaction cuvette, the probe transfers the reaction products to an analysis chamber (liquid analysis apparatus).

A preferred embodiment of the invention is illustrated in FIGS. 1-9. FIG. 1 shows a probe 10 for dispensing and aspirating liquid into and out of a vessel 14. Vessel 14 is held in a rack 16 which is mounted on a carousel. Probe 10 is attached to a probe positioning device, such as a mechanical arm 12. Arm 12 is designed to position probe 10 in an appropriate vessel for aspirating or dispensing liquid. Such mechanical arms for positioning probes are well known in the art.

FIG. 2 shows a cross sectional view of probe 10 (needle) and a portion of arm 12. Probe 10 includes an electrically insulative tube 18, an electrically conductive fluid conduit 26, and an electrically conductive rod 30. Conduit 26 and rod 30 are made of a relatively inert material so that they do not chemically react with sample and reagent liquids. The inert material is preferably stainless steel or gold-coated copper.

A washing station (rinsing means) is typically provided to wash the probe between aspirations of different substances.

3. Claims 3 and 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by King et al. US 6,132,582.

A sample handling system in a multi-channel capillary electrophoresis apparatus is disclosed. The sample handling system includes a work surface for supporting a plurality of samples located at a plurality of work surface coordinates (plurality of vessels) and a sample loading assembly comprising a plurality of loading wells. At least one of the loading wells includes a capillary fixedly positioned therein. The system further includes a programmable sample transfer device for **automatically transferring** a sample from a work surface coordinate to a loading well.

The material used to fabricate the pipette (needle) will depend upon the requirements of a particular application. Factors to be considered include wetability, rigidity and conductivity. Where the sample is a liquid, the wetability of the pipette should be such that sample may be introduced into the pipette in a controlled and reproducible manner. When the pipettes are passively loaded with sample using capillary action, generally the pipette should be wetable by the sample material. It is preferable that the pipette be rigid in order to facilitate location of the inlet end of the pipette with respect to the robot arm. Finally, where an electrical measurement is used in the tip sensor, the pipette should be electrically conductive. Preferred pipette materials include but are not limited to stainless steel, platinum and gold coated materials, glass, fused silica, and plastic or plastic coated materials, e.g., stainless steel coated with a parylene (synthetic resin).

The loading wells 20 located in the loading bar 150 include fluid passages 165 for introducing fluids into the loading wells, e.g., wash solvents for washing the loading wells between samples or electrophoresis buffer, and for removing fluids from the loading well, e.g., drying the loading wells after washing with wash solvents or removing residual sample after an injection step (column 7, line 65 – column 8, line 7).

Optionally, the sample loading assembly further provides a means for washing the exterior surface of a pipette associated with the sample transfer device 25. The capillary tubes 21 (liquid analysis apparatus) within which electrophoresis is performed are fixedly located in the loading wells during operation of the system (column 7, lines 49-55).

4. Claims 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. by US 6,365,024.

Li et al. discloses an automated electrophoretic system is disclosed. The system employs a capillary cartridge having a plurality of capillary tubes. The cartridge has a first array of capillary ends projecting from one side of a plate. The first array of capillary ends are spaced apart in substantially the same manner as the wells of a microtitre tray of standard size (plurality of vessels). This allows one to simultaneously perform capillary electrophoresis on samples present in each of the wells of the tray.

The separation process employs a capillary tube filled with conductive gel (liquid analysis apparatus). To introduce the sample, one end of the tube is placed into the DNA reaction vial. After a small amount of sample enters the capillary end, both capillary ends are then placed in separate buffer solutions. A voltage potential is then applied across the capillary tube. The voltage drop causes the DNA sample to migrate from one end of the capillary to the other.

FIG. 3A shows a needle 140 used in forming a tube assembly 160 which can then be directly inserted into a mounting plate 162, as shown in FIG. 3B. The needle 140 comprises a metallic cannula 142. In the preferred embodiment, the cannula 142 is formed from stainless steel having an inner diameter of 0.064 in. and an outer diameter of 0.072 in. The cannula 142 is provided with a bevel 144 at the end which is dipped into a well.

As is known to those skilled in the art, the voltage differential may be delivered to the first capillary ends through other means as well. For instance, instead of contacting

a common plate to which the needles are connected, voltage leads may be connected directly to each needle. Alternatively, individual leads may be dipped into the liquid in each well. Another alternative is to deliver the voltage through a metallic coating, such as gold, deposited on the exterior of only the terminal portion of each capillary tube, where it contacts the liquid in the well. Also, the voltage may be delivered directly to the wells through one or more leads, as described earlier. One skilled in the art can readily formulate alternative approaches to delivering a voltage to the first capillary end.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adrien Jr. et al. US 2002/0168778 in view of Sohrab US 6,793,632.

Adrien Jr. et al. disclose a reusable or disposable injector needle configured in an autoinjector or a manual injector which serves as the means to remove a sample solution from a container and transport such solution to an API source wherein the injector needle, when introduced into the API source, serves as the spray needle to deliver sample directly into the API source chamber. Such fixed or disposable injector needle, when introduced into an API source, becomes the liquid introduction channel or tube in the nebulizer probe of an APCI source, the nebulizer apparatus of a pneumatically assisted Electrospray probe or an Electrospray tip in an unassisted ES ion source probe. Ions produced from samples introduced through such sprayers into an API source are subsequently directed into vacuum where they are mass to charge analyzed. Ions transported into vacuum from such API source apparatus may also be subject to mass to charge selection and/or fragmentation in MS/MS analysis (paragraph 0009).

When a reusable needle is configured in the invention, the needle inner bore and outer surface can be washed (rinsing means) in between each sample delivery and

spraying step to reduce or eliminate, chemical noise, cross talk or carry over from one sample to the next (paragraph 0011).

Adrien et al. do not disclose the needle as comprising a resin coating is polyetheretherketone (PEEK).

Sohrab discloses a device for sampling at least one biological fluid constituent and measuring at least one target constituent within the biological fluid.

To be able to withstand a sterilization process the micro-needles and/or the array of micro-needles may be formed of or coated with an insulating material, such as a ceramic, glass, silica, polymer, plastics and the like. Examples of polymers are polyacrylates, epoxies, polyesters polyetheretherketone, liquid crystalline polyesters, or their composites.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the reusable needle of Adrien et al. by coating it with PEEK material in order to ensure the integrity of the needle is maintained throughout a sterilization/washing process.

Allowable Subject Matter

9. Claims 1 and 5 are allowed.

10. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach nor fairly suggest a needle having an outer surface coated with a coating material that includes a noble metal including platinum, a platinum group metal, or gold and interior surface coated with the same outer coating in addition

to a thin film of quartz and a needle containing a non-noble base metal that includes nickel or chromium.

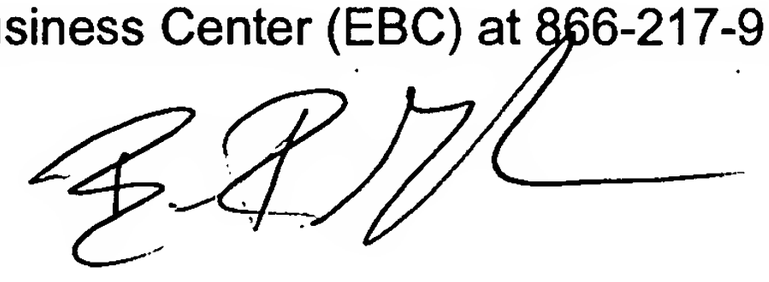
Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mimura; Tomonori et al.; Fujita; Hiroko et al.; Pennatto; Samson and Averette; Julius P: disclose automated analytical device including injectors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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